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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ashok C. Khandkar, et al

Serial No. 10/737,108

Filed: December 15, 2003

For: **TOTAL DISC IMPLANT**

Group Art Unit: 3738

Examiner: Blanco, J.G.

Docket No. 43662-Amedica

DECLARATION UNDER 37 CFR 1.131

MS: AF
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Ashok C. Khandkar, Darrel S. Brodke, and Ramaswamy Lakshminarayanan,
declare as follows:

1. We are the three named coinventors in U.S. Serial No. 10/737,108, filed at the
U.S. Patent & Trademark Office on December 15, 2003, and entitled TOTAL DISC
IMPLANT. This application Serial No. 10/737,108 claims the benefit of prior-filed U.S.

Serial No. 10/737,108

Provisional Appln. 60/434,092, filed December 17, 2002.

2. Two of the named co-inventors, Drs. Khandkar and Lakshminarayanan, are employees of Amedica Corporation, the owner by assignment of the entire right, title and interest in and to the invention disclosed and claimed in U.S. Serial No. 10/737,108. The third co-inventor, Dr. Brodke, is a consultant to Amedica Corporation. Amedica Corporation has a principal place of business in Salt Lake City, Utah. Each of us is a resident of Salt Lake City, Utah.

3. Serial No. 10/737,108 discloses and claims a total disc replacement (TDR) or implant defined by a articulatory or inter-engaging bearing components adapted for affixation to adjacent vertebral bodies such as patient bone structures. These bearing surfaces are defined by part-cylindrical or part-circular cross sectional shapes, and wherein at least one of these bearing surfaces is further defined by "laterally spaced-apart, offset radii to include a generally flattened base segment interposed between a pair of curved sides". See independent claims 1 and 42 as presented in the Response filed November 22, 2004.

4. This concept, namely, the inclusion of at least one bearing surface defined by "laterally spaced-apart, offset radii to include a generally flattened base segment interposed between a pair of curved sides", was conceived by us at Amedica Corporation in Salt Lake City, Utah, at least as early as February of 2002, in the course of a total disc replacement (TDR) development project.

5. More particularly, attached to this Declaration as Exhibit 1 (two pages) is a

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copy of a hand-prepared document including drawings and notes, dated February 26, 2002 ("2/26/02"). Exhibit 1 bears the heading "TDR Concept". Exhibit 1 shows the total disc replacement in one preferred form to include upper and lower end plates having convex articulation surfaces and each adapted for affixation to adjacent patient bone by means of porous bone ingrowth surfaces (porous CSC), together with an intermediate "bi-concave Insert". Thus, Exh. 1 shows the total disc replacement having two articulatory interfaces, namely, a first interface between the upper end plate and the upper surface of the bi-concave insert, and a second interface between the lower end plate and the lower surface of the bi-concave insert. Page 1 of Exh. 1 shows these components in an anterior-posterior (A-P) view, whereas page 2 of Exh. 1 shows these components in a medial-lateral (M-L) view.

6. Exhibit 2 (one page) attached to this Declaration is a copy of another hand-prepared document including drawings and notes related to the same total disc replacement concept. Exh. 2 bears the heading "TDR Design" and bears the date "Feb. 28, 2002". Exh. 2 (one page) outlines a concept for the specific geometry of the articulation interfaces for the "TDR Design", namely, the articulation interfaces shown in Exh. 1. Specifically in the medial-lateral (M-L) view as shown in Exh. 2, the above-noted "offset radii" concept is illustrated "to allow translation". This offset radii concept was and is designed to accommodate a limited degree of axial rotation between the engaged components, such as on the order of about +/- 6 to 10 degrees as noted on the exhibit.

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7. Exhibit 1 was prepared by Dr. Khandkar, and Exhibit 2 was prepared by Dr. Lakshminarayanan. Both Exhibits 1 and 2 were prepared in preparation for a meeting among the co-Inventors. See, for example, Exh. 2, and the notation "AK & Brodke". Both Exhs. 1 and 2 are made in Salt Lake City, Utah, USA, on the dates indicated thereon. Both Exhs. 1 and 2 have since their creation been retained within technical research notebooks at Amedica.

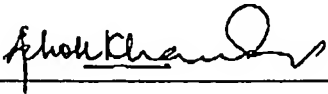
8. Exhibits 1 and 2 were discussed by the three co-inventors in Serial No. 10/737,108 in a meeting on February 28, 2002 and in numerous subsequent meetings as the total disc replacement concept was finalized preparatory to commercial activity as well as filing of a provisional patent application (on December 17, 2002). Such regular meetings occurred frequently from late February 2002 until the December 17, 2002 patent application filing date, and continued thereafter in connection with further product research and development, and commercialization.

We hereby declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true; and further that all these statements were made with the knowledge that willful false statements and the like to made are punishable by fine or Imprisonment, or both, under

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Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 4/26/, 2005



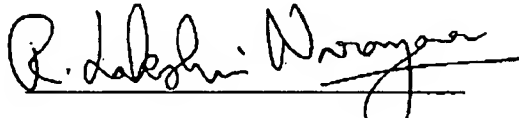
Ashok C. Khandkar

Date: 4/27/, 2005



Darrel S. Brodke

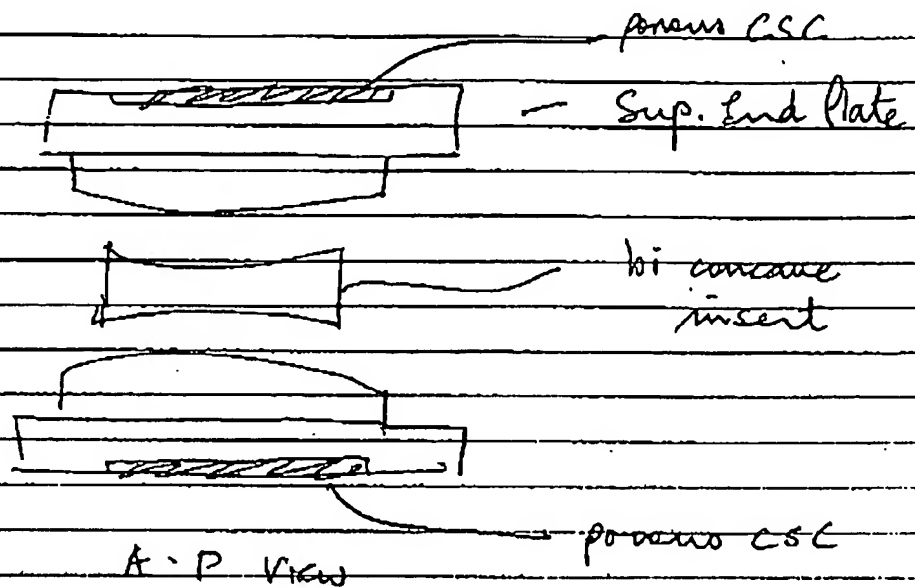
Date: 4/26/, 2005



Ramaswamy Lakshminarayanan

2/26/02

TDR Concept



Pros:

1. ingrowth surface for attachment to end plates
2. bi-concave insert - provides modularity
 - no revision of end plates
 - variable hts to suit anatomy

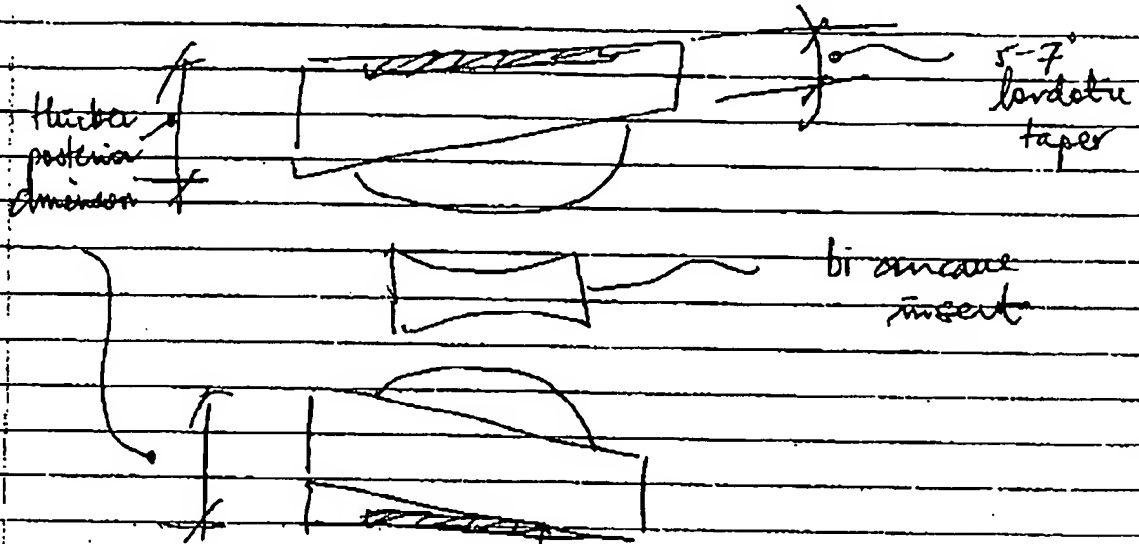
Cons:

- 3 piece
- possibility of expulsion of bi-concave insert?

EXHIBIT /
PAGE 7 OF 2

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M - L view



Pros

- Lordotic taper to suit anatomy

Cons of Design

- no axial limit?
- eg hard stop?

EXHIBIT 1
PAGE 2 OF 2

(2)

Feb 28 2002

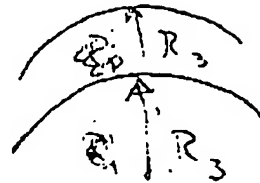
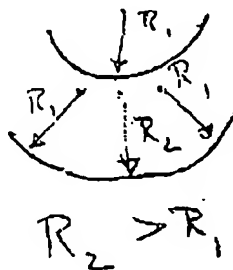
TDR Design

segments

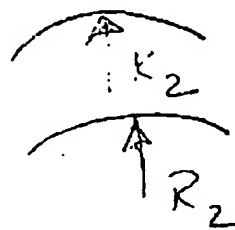
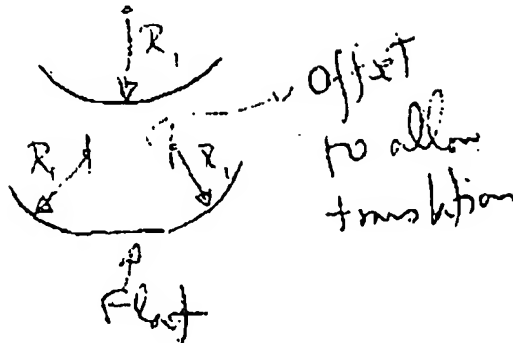
need AP Translation
limit axial rotation $\pm 6^\circ$ to $\pm 10^\circ$?

① M-L View

A - P View



②



Question? (AK & Burke)

2-piece vs 3-piece?

offset in one-side or both sides?

EXHIBIT 2
PAGE 1 OF 1